UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,684	10/25/2001	David P. Katz	AMBIINC.006A	3175

20995 7590 01/23/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/001,684	Katz, D.
Examiner	**Art Unit**
Patricia Patten	1654

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Nov 4, 2002* .

2a) This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-15* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) X Claim(s) *1-15* is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) X Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) X Information Disclosure Statement(s) (PTO-1449) Paper No.s). 7
4) Interview Summary (PTO-413) Paper No(s).
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

Claims 1-15 are pending in the application and were presented for examination on the merits.

Amendments to the claims 11/4/02 overcome the rejection under 35 U.S.C. 112 First paragraph.

Arguments received 11/4/02 were convincing. The previous rejection under 35 U.S.C. 102 (b) have thus been withdrawn. Arguments pertaining to this previous rejection are thus moot in light of the new rejections *infra*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ostlund et al. (US 5,550,166) .

Ostlund et al. disclosed a method for treating conditions associated with insulin resistance such as polycystic ovary syndrome via administration of a composition comprising pinitol (Abstract and lines 44-61). Ostlund et al. further taught that an enteral composition comprising pinitol also beneficially included chromium and selenium yeast (col.1, lines 43-61).

One of ordinary skill in the art would have been motivated to have administered a composition comprising selenium and chromium yeast and pinitol to a patient suffering from polycystic ovary syndrome in order to treat symptoms of insulin resistance such as hyperlipidemia and obesity. Ostlund et al. taught that this composition was advantageously administered enterally to treat symptoms of insulin resistance associated with polycystic ovary syndrome.

Although Ostlund et al. did not explicitly teach wherein a subject was identified who suffered from PCOS, one of ordinary skill in the art would have had a reasonable

expectation that administration of the enteral form of the drug which comprised selenium and chromium yeasts would have beneficially effected a patient with PCOS by reducing symptoms associated with insulin resistance. 'Identifying' the subject with PCOS would have been obvious to one of skill in the art because one would have wanted to positively identify that the patient had PCOS prior to treatment in order to create a positive effect with regard to treating insulin resistance in said patient.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over de la Harpe et al. (US 5,980,905) in view of Ostlund et al. (US 5,550,166).

De la Harpe et al. (US 5,980,905) disclosed that chromic polynicotinate and chromic tripicolinate were well known in the art for lowering blood glucose levels and lowering serum lipid levels (col.5, lines 45-51). De la Harpe et al. further disclosed that The chromic tripicolinate and chromic polynicotinate facilitate absorption of chromium by intestinal cells, while the additional picolinic acid and/or nicotinic acid in the composition facilitates absorption of other ingested chromium as well as other metals including....copper, iron, magnesium, manganese and zinc" (col.4, lines 18-24). The composition further included a cyclooxygenase inhibitor such as ibuprofen or acetaminophen, a mucolytic such as gaifenesin and a salicin-containing herb such as

Boswellia seratta (col.3, lines 14-29 and claims 1-7 which specifically claim the composition).

De la Harpe et al. further taught wherein the effective dose was between about 50 and 10,000 micrograms (lines 31-36) and wherein the composition was incorporated into a microbead wherein the chromium complex was coated on the beadlet (claims 9 and 10 for example).

De la Harpe et al. did not explicitly teach wherein the composition was administered to a patient suffering from PCOS nor wherein the ratio of chromium complex to chelating agent was about 1:10 and about 10:1.

Ostlund et al. disclosed a method for treating conditions associated with insulin resistance such as polycystic ovary syndrome via administration of a composition comprising pinitol (Abstract and lines 44-61). Ostlund et al. taught that polycystic ovary syndrome was associated with insulin resistance which manifested symptoms such as diabetes and hyperlipidemia (col.3, lines 42-55). Ostlund et al. further taught that an enteral composition comprising pinitol also included chromium and selenium yeast (col.1, lines 43-61).

One of ordinary skill in the art would have been motivated to have administered a composition comprising a chromium complex, a chelating agent such as picolinic acid, a salicin-containing herb such as Boswellia serrata, a cyclooxygenase inhibitor such as ibuprofen or acetaminophen, a mucolytic such as guaifenesin all in a microbead form wherein the composition is coated on said beadlette to a patient suffering from PCOS in order to alleviate symptoms of hyperlipidemia, diabetes and obesity for example.

The ordinary artisan would have had a reasonable expectation that because de la Harpe et al. taught that the composition was beneficial in treating blood glucose levels and serum lipid levels as well as increasing lean body mass, that these symptoms could have been treated in a patient suffering from PCOS because PCOS patients display these symptoms as disclosed by Ostlund et al.

One of ordinary skill in the art would have been motivated to have adjusted the concentration of chromium complex to chelating agent in order to optimize the effectiveness of the composition, thereby creating a product with greater efficiency to treat obesity, hyperlipidemia and increased blood glucose levels. Although neither reference specifically taught wherein the ratio of chromium complex and chelating agent are administered in a ratio of between about 1:10 and about 10:1, this claimed ratio is very broad. Because de la Harpe et al. taught that administration of the chelating agent

along with the chromium complexes advantageously sequestered metal ions to facilitate their absorption, variation of the amounts of chromium complex with respect to the chelating agent would have been routine optimization of result effective variables.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

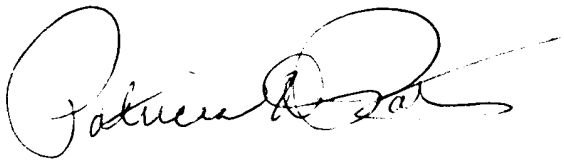
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

January 16, 2003



Patricia Patten